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10/007,457	11/08/2001	Aiden Flanagan	10177-058	3341

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EXAMINER
MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
1762	

DATE MAILED: 09/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/007,457	FLANAGAN, AIDEN
	Examiner	Art Unit
	Jennifer Kolb Michener	1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 08 November 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 13-36 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-7, 11 and 12 is/are rejected.

7) Claim(s) 8-10 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Election/Restrictions

1. Examiner notes Applicant's election of Group I, claims 1-12 with appreciation. Since Applicant did not indicate whether election was with or without traverse, Examiner has interpreted the response to be without traverse.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Graves et al. (5,925,069).

Graves teaches a method of applying a biologically active coating material to an implantable medical device, such as a stent, and selectively ablating an amount of coating in excess of the desired coating amount (col. 3, lines 38-45 and 58-66; col. 4, line 5 and line 27; col. 6, lines 15-17, 23, 29, 45-48; col. 8, lines 37-45; col. 9, lines 10-

30). Since Graves teaches removal of the desired amount of excess bio-active coating, Graves inherently teaches first applying an excess amount of coating. Because Graves selectively removes the excess, his process inherently determines and selects the amount in excess to be removed. Graves teaches using an ultraviolet, excimer laser, as required by the claim (col. 6, line 29).

Stents are “curved” as required by claim 4.

Graves teaches ablating the coating in a manner which leaves the underlying substrate unaffected, as required by claim 5 (col. 8, line 44).

4. Claims 1, 4, 5, and 12 are rejected under 35 U.S.C. 102(e) as being unpatentable by Harish et al. (US 6,503,556 B2).

Harish teaches coating a stent with a polymer and bioactive agent composition in the form of a sheath (abstract; col. 5). The sheath covers the entire stent, including the gaps between the struts of the stents. Harish teaches the use of an excimer laser in removing portions of the coating sheath that cover the gaps to yield the stent pattern of interstices (paragraph bridging columns 8 and 9). Since Harish teaches removal of coating material in excess of that which is desired in the final coating, Harish inherently teaches first applying an excess amount of coating in the form of his sheath. Because Harish selectively removes the excess, his process inherently determines and selects

the amount in excess targeted for removal. Excimer lasers are ultraviolet, as required by the claim.

Stents are curved, as required by claim 4.

Because the excimer laser is only applied in the gapped regions, the underlying substrate is inherently not ablated, as required by claim 5.

Regarding claim 12, Harish teaches a polymeric portion of the coating material comprising, for example, poly-L-lactic acid, among others (col. 4, line 7).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 2, 6, 7, and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Graves.

Graves teaches that which is disclosed above, but fails to teach the pulse length, frequency, and wavelength of the ultraviolet laser, as required by claims 2 and 11.

It is the Examiner's position that selection of these laser variables would have been selected and optimized by an ordinary artisan based on the type of coating being ablated in order to optimize cost, time, and preservation of the delicate bio-active coatings.

It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 6, requiring the ablation step to only be conducted on an outermost layer of the coating, Graves fails to specifically teach a multi-layer coating.

However, it is Examiner's position that the use of two thinner layers of bioactive coating instead of using one thicker layer would have been an obvious interchangeable variable to one of ordinary skill in the art. In general, the transposition of process steps or the splitting of one step into two, where the processes are substantially identical or equivalent in terms of function, manner, and result, was held to not patentably distinguish the processes. *Ex parte Rubin*, 128 USPQ 440 (Bd. Pat. App. 1959). The splitting of one layer into two would have been obvious to an ordinary artisan with the expectation of similar results.

Additionally, Graves teaches that the excimer laser is used for a sufficient time to remove a desired thickness of the coating (col. 3, line 66). Therefore, since it's obvious for said coating to comprise more than one layer, and Graves teaches ablating only down into a certain portion of said coating, Graves teaches the ablation on "only the outermost layer of the coating".

Regarding claim 7, as outlined above, Graves teaches ablating away a desired portion of the coating that is inherently in "excess" to achieve a desired coating amount. While Graves does not specifically teach repeating the ablation step until the desired amount of coating remains, it is Examiner's position that splitting one ablation step into two would have been obvious to one of ordinary skill in the art for those reasons outlined

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above. If an ordinary artisan, desiring to achieve a certain reduction in excess coating, finds that the first ablation step is unsuccessful at fully achieving that goal, a second ablation step would have been a remedy obvious to that artisan.

9. Claims 2, 7, and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Harish.

Harish teaches that which is disclosed above, but fails to teach the pulse length, frequency, and wavelength of the ultraviolet laser, as required by claims 2 and 11. It is the Examiner's position that selection of these laser variables would have been selected and optimized by an ordinary artisan based on the type of coating being ablated in order to optimize cost, time, and preservation of the delicate bio-active coatings. It is well settled that determination of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Regarding claim 7, as outlined above, Harish teaches ablating away a desired portion of the coating that is inherently in "excess" to achieve a desired coating amount. While Harish does not specifically teach repeating the ablation step until the desired amount of coating remains, it is Examiner's position that splitting one ablation step into two would have been obvious to one of ordinary skill in the art for those reasons outlined above. If an ordinary artisan, desiring to achieve a certain reduction in excess coating, finds that the first ablation step is unsuccessful at fully achieving that goal, a second ablation step would have been a remedy obvious to that artisan.

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graves in view of Howarth (4,957,770).

Graves teaches that which is disclosed above, i.e., removing a desired amount of excess coating material from a stent, but fails to teach a method of determining the amount of bio-active material that is in excess.

Howarth teaches a method of weighing a coated article before and after coating to determine the actual coating basis weight of the applied coating for comparison with a desired coating basis weight (col. 2, lines 48-65).

Since Graves teaches a method of targeting and removing excess coating material from a coated substrate and Howarth teaches the use of coating weight, determined by weighing an article before and after coating, to determine a desired amount of coating, Howarth would have reasonably suggested the use of a weight basis in determining how much coating to ablate from the medical devices of Graves. It would have been obvious to one of ordinary skill in the art to use the teachings of Howarth in the method of Graves to provide Graves with a simple, effective weight basis method for determining the amount of excess coating applied to a stent to target for ablation.

Allowable Subject Matter

11. Claims 8, 9, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The closest prior art of record fails to teach, in combination with the method of claim 1, the determination of excess coating by coating and ablating a second medical device and measuring the height difference of the two coating layers using a white light interferometer.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Saunders teaches a pattern ablated in a stent coating. Lau teaches laser patterning a stent pattern. Hossainy '252 teaches removal of excess coating by shear force. Duhamel is cited for teaching the undesirability of excess coating material remaining on medical devices. Swain is cited for a generic teaching of the use of a laser to remove excess coating. Hossainy '733 is cited for teaching the use of a laser to remove maskant material from a stent and to form depots therein.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 11, 2003